

## **DRCRnet Site Visit Procedures**

### **A. Introduction**

Careful adherence to common protocols at every level of patient management and data collection is essential in large cooperative trial networks such as the DRCRnet. The quality of data depends upon uniformity of observations and treatment techniques. The ultimate responsibility for seeing that each staff member of a participating clinic is thoroughly familiar with protocols and that care is taken to implement each aspect rests with a clinic's Principal Investigator. The site's Clinic Coordinator not only should assist the PI in identifying and resolving problems, but serves as the key staff member at the clinic in regard to adherence to protocols.

Experience in large multi-center studies has shown that prompt resolution of problems involving personnel, space, equipment, protocol interpretation, etc. will be facilitated by regular frequent contact between the personnel at each study clinic and the central study administration. For the DRCRnet, a Site Monitor will be designated to visit each clinic at a predetermined frequency based on the protocol.

### **1. Definition**

A site visit is a visit to a clinical center in a trial or trial network for the purpose of assessing its performance.

- a. Initial** - the first assessment visit to a clinical center with a concentration on the basic clinical aspects of personnel, facilities, equipment, and preparedness to follow protocol
- b. Follow-up** - subsequent regular visits to a clinical site to monitor progress in meeting the goals of the protocols in which that clinic participates
- c. Special** - monitoring visits scheduled for the specific purpose of evaluating suspected problems and/or protocol violations at a site

### **2. Description**

Those making the site visit may be from another clinic center within the DRCRnet or someone in an administrative role within the network. There may be more than one person involved as a visiting "team".

There will be a formal agenda prepared for the site visit and a report written following the site visit. The report will be sent to the Principal Investigator (PI) at the clinic, evaluated, as well as becoming a part of the administrative documentation of the DRCRnet. All site visit reports may also be reviewed by the DRCRnet Executive Committee.

### **3. Scheduling**

Coordination of site visits will be the responsibility of the DRCRnet Coordinating Center. Regular site visits (either initial or follow-up) will be scheduled sufficiently in advance so that the clinic center's staff can make arrangements to be available. Special site visits may be done on short notice as the situation warrants. A hard copy of a regular site visit agenda will be sent to the clinic PI, the Clinic Coordinator, and the appropriate DRCRnet

Protocol Study Chairman (if required). A regular site visit is expected to occupy at least half of one day (possibly more if study patients are seen at more than one office location).

#### **4. Qualifications of Site Visitors**

A site visit will be conducted by one or more site visitors. When more than one individual is conducting the site visit, one of them will be designated as the primary site visitor responsible for the monitoring aspects of the visit.

Primary site visitors will be selected and, where indicated, trained by the Coordinating Center. Qualifications will include knowledge of the monitoring requirements of clinical trials and experience in conducting site visits (this may be in other studies or by attending DRCRnet site visits as a nonprimary site visitor).

### **B. Components**

#### **1. General**

The visits will include contacts with members of the clinic staff and essential support personnel for the clinic's participation in the DRCRnet. The visit may involve any or all of the following activities:

- Meeting with the site DRCRnet PI and site Coordinator
- Meeting with other site DRCRnet staff personnel (including refractionists & visual acuity testers, photographers, OCT technicians and financial administrator)
- Verifying presence and use of current versions of DRCRnet protocols and manuals
- Reviewing pertinent regulatory documents
- Reviewing of drug accountability procedures, supplies and logs (if applicable)
- Reviewing patient charts to determine whether information pertinent to the study protocols is present that is not part of the DRCRnet electronic case report form record (since the electronic CRF is considered the primary source for study data, a site may or may not have other medical records to be reviewed)
- Reviewing patient eligibility determination and consenting procedures being employed for the DRCRnet at the site
- Conducting private conversations with any DRCRnet staff personnel to assess practices and philosophy with regard to following protocols and data collection for the DRCRnet
- General assessment of clinic facilities, regular exam and study equipment, patient flow, documentation procedures and study record storage relating to the DRCRnet
- Refraction certification/recertification as appropriate

#### **a. Site Documents**

Assessments may include checking for the presence, accessibility, and current versions of hard copies of the following:

- General DRCRnet manuals (i.e. Testing Procedures Manual or Coordinator's Manual)
- Numbered DRCRnet memos
- Site's regulatory file (i.e. copies of IRB approvals, renewals and SAE submissions)
- Review and use of current, approved ICF, as well as any other consents (HIPPA, ancillary study)
- Personnel certification documentation
- Investigator biosketches and current medical licenses
- DRCRnet policies document
- Signed DRCRnet Investigator's Agreements
- Ethics Training Certification for all key study personnel
- Signed investigator Financial Disclosure Statements

#### **b. Patient Recruitment**

Review with investigators and Clinic Coordinator may include patient recruitment strategies being used by that clinic for the various DRCRnet protocols in which they participate.

#### **c. Patient Consenting**

The procedure, timing, physical location, personnel, and actual documents used for DRCRnet patient consenting will be reviewed.

### **2. Personnel**

The presence of and certification for all DRCRnet personnel at the site may be checked. This includes MDs, Clinic Coordinator, refractionists & visual acuity testers, and photographers & OCT technicians.

### **3. Facilities**

The physical facilities of each clinical site will be evaluated for the following aspects:

- a. Patient flow** - the movement and logistics of a study patient's typical new and/or follow-up evaluation as well as any treatment visits through the clinic
- b. General exam space** - history taking area as well as actual MD exam area to include wired/wireless internet connections
- c. Treatment area** - to include laser treatment area and equipment (including angiogram viewer) as well as procedure location for other treatments (e.g. intraocular steroid injections)

- d. Visual function testing space** - to include room size, lighting, trial lenses & frames, +\-.37 spherical lenses, manual Jackson cross cylinders, EVA testing equipment (including cart, CPU, monitor, calibration equipment & light meter, Palm Pilot), and back-up ETDRS charts/lightbox
- e. Photography/OCT capabilities** - to include location, equipment (cameras as well as OCT), film developing procedures, patient data (FAs, fundus photo slides, OCT files) handling and security
- f. Clinic Coordinator office** - to include size, location, phone/fax/computer capabilities, security, privacy, file space, and DRCRnet tablet PC
- g. Storage** - to include study documents as well as patient files, medications (non-food lockable refrigerator for IO steroids), study equipment (e.g. Eva & Palm, ETDRS charts & lightbox, tablet PC) when not in use, and security of all
- h. PC Tablet Configuration** - examine wireless or hard-wired connection(s) set-up and procedures used for data entry

### **C. Refraction Certification/Recertification**

If appropriate and applicable, pending time available during the site visit, certification or recertification for DRCRnet refractionists at the clinic may be done. As with the DRCRnet phone certification process for refraction certification, all candidates must have had requests submitted in advance of the site visit to the DRCRnet Coordinating Center and be fully prepared to exhibit comfort and expertise with the refraction protocol found in the DRCRnet Testing Procedures Manual.

**D. Site Visit Checklist – a template checklist is provided as Attachment 1.**

**E. Site Visit Agenda – a template of an agenda is provided as Attachment 2. The agenda will be modified according to the protocol.**

**F. Site Visit Report – a template report format is provided as Attachment 3.**

## Attachment 1 - Site Visit Checklist

Name of Investigator: \_\_\_\_\_  
Site Location: \_\_\_\_\_  
Name of Site Visitor(s): \_\_\_\_\_  
Target Visit Dates: \_\_\_\_\_

- \_\_\_\_\_ Send communication to site requesting potential available dates/times for a site visit.
- \_\_\_\_\_ Confirm date/time of site visit with clinical site.
- \_\_\_\_\_ Provide confirmation letter to site including requirements and documents/equipment for review:
  - Confirm availability of investigator/coordinator
  - Confirm availability of certified DRCRnet personnel
  - Confirm availability of meeting appropriate meeting space
  - Arrange lunch (if appropriate)
  - Specify study documents that will need to be available for review
  - Specify equipment available for inspection (tablet PC, refraction/VA testing equipment)
  - Specify patient charts that will need to be available for review
  - Specify tour will be required (including patient lanes, drug storage)
- \_\_\_\_\_ Send reminder of site visit 1 week prior
- \_\_\_\_\_ Following visit, send correspondence and review of visit